Diet Assessment System for Cancer Control Applications

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Abbreviated Abstract

This Phase II focused on the development of the Graphical Food Frequency System (GraFFS, commercial product names VioWell, VioScreen, VioFFQ), a comprehensive system for collecting data on dietary behavior and food use patterns, estimating nutrient intake, and delivering an interactive dietary change intervention. GraFFS is being developed to improve dietary assessment in studies on diet and cancer, and to make it cost-effective and feasible to include "tailored" behavior feedback based on comprehensive dietary assessment as a component of both clinical and population-based cancer control interventions. The complete system will: (a) use a graphical, touch-screen, food frequency questionnaire (FFQ)-based method for data collection; (b) generate reports on nutrient intake and food use patterns suitable for a variety of clinical counseling and research applications; and (c) deliver a theory-based, interactive behavioral intervention that is tailored to the respondent's dietary patterns and dietary goals. Innovations include: (a) computer-aided self-interview technology that will significantly improve the quality of FFQ-based dietary assessment; (b) system customizability, to allow flexibility to capture regional/ethnic food patterns, use different languages and font sizes, and focus on specific nutrients and food components; and (c) sophisticated and validated methods for tailoring behavioral feedback that is delivered as an interactive intervention. Phase II work will complete the system for data collection, nutrient analysis and behavioral intervention, which will be followed by a validation study to examine the inter-method reliability of GraFFS vs. multiple 24-hour recalls and a pilot study to examine the feasibility and potential efficacy of GraFFS to promote healthful dietary change among survivors of prostate, colorectal, and breast cancers.

This Phase II SBIR project is currently active and in its second year. Phase I resulted in two commercial products, VioScreen (clinical) and VioFFQ (research).

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Total Budget

$1,527,304

Research Objectives

AIMS

1) To complete the GraFFS system's graphical interface to include food pictures and portion size pictures.
2) To complete an interactive, theory-driven, tailored behavioral intervention system. The dietary goals for this Phase II proposal will focus on dietary changes most relevant to cancer control (increasing phytochemical-rich vegetables and fruits, increasing whole grain foods, and decreasing total and saturated fats).
3) To complete a system allowing researchers and/or clinical administrators to customize the system for their unique needs. Using system-supplied "profiles," administrators can select features that focus the dietary assessment and/or behavioral feedback on (a) specific nutrients or dietary behaviors; (b) specific ethnic and regional dietary patterns; and (c) unique population subgroups.
4) To complete the customization tool that will enable support staff to create custom profiles as requested by system users. These profiles would include new questionnaires (add or delete food items and to modify portion size options), new languages and custom analyses (e.g., user-supplied databases).
5) To complete a study of 100 men and women to examine the validity (inter-method reliability) of GraFFS vs. multiple 24-hour dietary recalls.
6) To complete a pilot study in 75 men and women to determine the feasibility, acceptability and potential efficacy of using GraFFS for promotion of low-fat diets in survivors of breast, colorectal, and prostate cancers.

Theory/Hypothesis

A computerized, graphical, pictorial approach to collecting food intake information, which also allows customization to address different languages, regional and ethnic dietary patterns, and research foci, can dramatically improve the quality of FFQ-based dietary assessment. Further, a system that supports immediate analysis and generates output useful for nutritional counseling can enhance the effectiveness of clinical dietetics practice. Finally, a system that generates "tailored" feedback and delivers this feedback in the context of an interactive and theory-driven intervention to promote dietary behavior change can be used as an intervention component in clinical and community-based cancer control interventions. Computer-generated tailored feedback can be produced based on an individual's dietary patterns, while incorporating messages to enhance self-efficacy and motivation for change.

Experimental Design

Evaluations include a validity study to evaluate the measurement characteristics of the GraFFS as a dietary assessment tool, and a study to evaluate the feasibility and potential efficacy of the GraFFS to promote healthful dietary change in cancer survivors.

Final Sample Size & Study Demographics

Two studies will be completed in 2009 by The Ohio State University. The demographics will be based on the population of the Columbus, Ohio metropolitan area 19.9% African-American, 6.8% Hispanic or Latino, 3.1% Asian, and 0.3% American Indian or Alaskan Native, with the remainder being White. Individuals will be recruited for two studies, a validation study and a feasibility/pilot efficacy study.

Participants in the validation study will be 50 men and 50 women living in the Columbus area, who are interested in receiving a comprehensive dietary evaluation. The participants within the validation study will be healthy individuals, able to read and write English, from 18 to 70 years of age, recruited within the following three age groups in equal numbers, 18-39, 40-54, and 55-70.

The purpose of feasibility and pilot efficacy study is to evaluate how GraFFS performs when used as an intervention tool in women treated for early-stage breast cancer and men treated for early stage prostate cancer. The participants for this study will consist of 75 men and women treated for early-stage breast cancer, colorectal, or prostate cancer. Participants will all be between 1 and 5 years post diagnosis and 45 to 70 years of age.

Data Collection Methods

Validity study participants will complete a GraFFS session (a web-based self-administered FFQ representing intake over the past 3 months) at study entry, over the next 3 months they will complete 8, telephone administered 24-hour dietary recalls, and then at end of the study will complete an additional GraFFS session. Recalls will be administered without prior notification, and will include at least 3 weekend days.

The efficacy participants will be randomized to the intervention or delayed intervention arm. At baseline, all participants will complete the GraFFS dietary assessment component, but only those in the intervention arm will continue in GraFFS to the interactive behavioral feedback system. Intervention arm participants will also receive 3 reminders to enhance motivation and self-efficacy, which will be generated by the system and sent via email. At three months post-randomization, all participants will again complete the GraFFS dietary assessment component. Those in the intervention arm will continue in the interactive feedback, which will be incorporate information from the previous session, while those in the comparison arm will continue to their first use of the feedback system. Following both the baseline and the follow-up GraFFS administrations, all participants will complete a questionnaire for process evaluation.

Outcome Measures

The validation study will assess the reliability of the GraFFS by comparing the measures from the first and second administrations, using the intraclass correlation coefficient. We will calculate intraclass correlation coefficients and their lower confidence bounds for those dietary measures relevant to giving behavioral feedback on cancer prevention (see table). In addition, we will divide participants into quartiles of intake based on the first and second GraFFS administrations and compare these using weighted kappas.

% Energy from Total Fat	Omega-3 Fatty Acids	Servings of vegetables
% Energy from Saturated Fat	Fiber	Servings of fruits
Glycemic Index	Folate	Servings of Cruciferous Vegetables
Trans-fatty acids	Calcium	Alcohol

Endpoints for efficacy evaluation will be change in percentage energy from fat and change in consumption of fruits and vegetables.

Evaluation Methods

We will assess the validity (bias and precision) of GraFFS by comparing the dietary measure from the first GraFFS administrations (X_1) to the measure from the combined eight 24-hour dietary recalls (X_2). Systematic bias (GraFFS versus the recalls) will be assessed as the difference between the mean GraFFS measure the mean measure from the eight, 24-hour dietary recalls: $X_1 - X_2$. We will compute a confidence interval around this mean difference based on a one sample t-test on the variable (X_{i1}-X_{i2}) computed for each participant i. The Pearson correlation coefficient between X_1 and X_2, and its lower 95% confidence bound will assess precision. We will estimate bias and Pearson correlation coefficients for each dietary measure listed in table above. Those nutrients that are positively skewed will be transformed for computation of the Pearson correlation. We will also compute weighted kappas after categorizing participants into quartiles based on X_1 and quartiles of X_2. All analyses will then be repeated comparing the second, end-of-study GraFFS assessment to the 24-hour recalls. This is more appropriate because it covers the time period during which 24-hr recalls are collected, but the resulting intake data are not strictly generalizable because participants will have "trained" by completing the first GraFFS and by being intensively monitored for diet.

Criteria for assessing the measurement characteristics (e.g., validity and reliability) of the GraFFS will be based on comparisons of results of this validation study with those from similar studies of other FFQ-type instruments. In general, reliability as assessed by the intraclass correlation of FFQ-derived measures of energy-adjusted macronutrients, fruit and vegetable consumption, and micronutrients such as calcium and folate are 0.6 and above. Comparing validity across studies is complex, because of variations in both the numbers of 24-hour recalls used to define usual intake and statistical methods used to compute validity (or more accurately termed inter-method reliability). Thus, while we will report raw correlations between the GraFFS and 24-hour recall derived nutrients, we will base comparisons on correlations adjusted for measurement error in the 24-hour dietary recalls. Based on the literature and on results from previous studies of Fred Hutchinson Cancer Center Questionnaires, we expect adjusted correlations of 0.65 and higher for energy-adjusted macronutrients, 0.6 and higher for calcium, folate and fiber, 0.5 and higher for fruit and vegetable consumption, carotenoids, and tocopherols.

All efficacy evaluation analyses are "intent to treat," and are based on the difference in changes between groups. This measure, often termed the "intervention effect," for fat is defined as follows:

$$((Fat(\%en)_1)_b - (Fat(\%en)_1)_f)_I - ((Fat(\%en)_1)_b - (Fat(\%en)_1)_f)_P$$

where the subscripts *b* and *f* refer to baseline and follow-up, and the subscripts *I* and *D* refer to intervention and delayed intervention contrast groups. The statistical evaluation will be based on a multiple regression analysis, in which the dependent variable will be difference in fat(%en) between baseline and the 3-month follow-up, and the independent variables will be fat(%en) at baseline and an indicator variable for treatment arm. In this model, the regression coefficient for the indicator variable is the intervention effect, and the standard error of the regression coefficient is used to evaluate the variability in this effect. Both statistics give an indication of the potential efficacy of the GraFFS when used as an intervention tool. We do not expect differences to be statistically significant, and the purpose of calculating these statistics is to aid the design of a definitive evaluation.

Research Results

Results are expected in 2009

Barriers & Solutions

Currently have not encountered any barriers or limitations to overcome

Product(s) Developed from This Research

VioWell (corporate wellness), VioScreen (clinical), VioFFQ (research)